Complete Summary

GUIDELINE TITLE

Preconception care of women with diabetes.

BIBLIOGRAPHIC SOURCE(S)

Preconception care of women with diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S76-8. [2 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Pregnancy
- Diabetes mellitus

GUIDELINE CATEGORY

Evaluation
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Physician Assistants
Physicians
Social Workers

GUIDELINE OBJECTIVE(S)

- To define the elements of a preconception care program
- To describe the recommended intensive outpatient treatment plan, based on risk assessment, health promotion, and intervention, and to outline effective team work strategies to implement the plan before and during early pregnancy

TARGET POPULATION

Diabetic women of child-bearing age

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Evaluation During Initial Physician Office Visit

1. Medical and obstetric history
    - Duration and type of diabetes
    - Acute and chronic complications
    - Diabetes management
    - Concomitant medical conditions and medications
    - Menstrual/pregnancy history; contraceptive use
    - Support system
2. Physical examination
    - Ophthalmic evaluation
    - Cardiovascular exam
    - Neurologic exam
3. Laboratory evaluation
    - Glycated hemoglobin (HbA1c)
    - Serum creatinine and urinary excretion of total protein and/or albumin
    - Serum thyroid stimulating hormone and/or free thyroxine level
    - Other tests as indicated by physical exam or history

Preconception Risk Prevention and Management

1. Multidisciplinary team planning
2. Intensive outpatient treatment plan
3. Counseling
    - Risk of malformations associated with unplanned pregnancies and poor metabolic control
    - Contraception
    - Counseling by a mental health professional when indicated to reduce stress and improve adherence to the diabetes treatment plan.

4. Anti-hyperglycemic therapy (insulin or oral antidiabetic agents)
5. Patient education
    - Interaction of diabetes, pregnancy, and family planning
    - Use of an appropriate meal plan
    - Self-monitoring of blood glucose
    - Self-administration of insulin and self-adjustment of insulin doses
    - Treatment of hypoglycemia (patient and family members)
    - Incorporation of physical activity
    - Development of techniques to reduce stress and cope with denial
6. Follow-up after initial management plan established
    - Office visits at 1-2 month intervals
    - Phone contact

MAJOR OUTCOMES CONSIDERED

- Risk and rate of congenital malformations
- Risk and rate of early pregnancy loss
- Health care costs
- Glycemic control during the preconception period

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

To prevent excess spontaneous abortions and congenital malformations in infants of diabetic mothers, diabetes care and education must begin before conception. This is best accomplished through a multidisciplinary team approach including a diabetologist, internist, or family practice physician skilled in diabetes management; an obstetrician familiar with high-risk pregnancies; diabetes educators including registered nurse, registered dietitian, and social worker; and other specialists as necessary. Ultimately, the woman with diabetes must become the most active member of the team, calling upon the other members for specific guidance and expertise to help her toward her goal of a healthy pregnancy and newborn.

Practical self-management skills essential for glycemic control and preparation for pregnancy include the following:

- Use of an appropriate meal plan
- Self-monitoring of blood glucose (SMBG)
- Self-administration of insulin and self-adjustment of insulin doses
- Treatment of hypoglycemia (patient and family members)
- Incorporation of physical activity
- Development of techniques to reduce stress and cope with denial

Initial Physician Office Visit

Medical and Obstetric History

A complete history is imperative before planning for pregnancy. This should include, but not be limited to, questioning for the following:

- Duration and type of diabetes (type 1 or type 2)
- Acute complications, including history of infections, ketoacidosis, and hypoglycemia
- Chronic complications, including retinopathy, nephropathy, hypertension, atherosclerotic vascular disease, and autonomic and peripheral neuropathy
- Diabetes management, including insulin regimen, prior or current use of oral glucose-lowering agents, self-monitoring of blood glucose regimens and results, medical nutrition therapy, and physical activity
- Concomitant medical conditions and medications, thyroid disease in particular for patients with type 1 diabetes
- Menstrual/pregnancy history; contraceptive use
- Support system, including family and work environment

An initial individual educational evaluation session with a diabetes educator, a registered dietitian, and, when needed, a psychosocial expert is valuable. Members of the patient's immediate family should participate in this session. In conjunction with the primary physician, these professionals will review the patient's current management plan and develop a comprehensive treatment plan.

Physical Examination

Diabetic retinopathy, nephropathy, autonomic neuropathy (especially gastroparesis), and coronary artery disease can be affected by or can affect the outcome of pregnancy, Thus, physical examination should give particular attention to the following:

- Blood pressure measurement, including testing for orthostatic changes
- Dilated retinal exam by an ophthalmologist or other eye specialist knowledgeable about diabetic eye disease
- Cardiovascular exam for evidence of cardiac or peripheral vascular disease. If found, patients should have screening tests for coronary artery disease before attempting pregnancy to assure they can tolerate the increased cardiac demands.
- Neurological exam, including examination for signs of autonomic neuropathy

Laboratory Evaluation

The evaluation should focus on assessment of metabolic control and detection of diabetic complications that may affect or be affected by pregnancy:

- Glycated hemoglobin (HbA1c)
- Serum creatinine and urinary excretion of total protein and/or albumin (albumin-to-creatinine ratio or 24-hour excretion rate). Patients with protein excretion >190 mg/24 hours have been shown to be at increased risk for

hypertensive disorders during pregnancy. Patients with protein excretion >400mg/24 hours also are at risk for intrauterine growth retardation during later pregnancy. No specific treatments are indicated, but patients should be counseled about these risks. Since patients should not take angiotensin-converting enzyme (ACE) inhibitors during pregnancy, these assessments should be carried out after cessation of these drugs.

- Measurement of serum thyroid stimulating hormone and/or free thyroxine level in women with type 1 diabetes because of the 5 to 10% coincidence of hyper- or hypothyroidism
- Other tests as indicated by physical exam or history

Management Plan

The initial management plan should include the following components:

- Counseling about the risk and prevention of congenital anomalies; fetal and neonatal complications of maternal diabetes; effects of pregnancy on maternal diabetic complications; risks of obstetrical complications that occur with increased frequency in diabetic pregnancies (especially hypertensive disorders); the need for effective contraception until glycemia is well-controlled; and the cost-benefit relationship between preconception care and prevention of malformations.
- Selection of anti-hyperglycemic therapy. Insulin should be prescribed for type 1 and type 2 patients, because the safety of currently available oral antidiabetic agents is not assured during early pregnancy.
- Establishment of plan to achieve low-risk glycemia. The main tool for assessing the risk of malformations in the infant is the maternal glycated hemoglobin concentration. Two steps are recommended for achieving a low-risk concentration (less than 1% above the normal range, lower if possible).

1. Set goals for self-monitored glucose. Successful preconception care programs have used the following pre- and postprandial goals:

   Before meals: capillary plasma glucose 80-110 mg/dL (4.4-6.1 mmol/L).

   2 h after meals: capillary plasma glucose <155 mg/dL (<8.6 mmol/L) at 2 hours.

   There are no data to suggest that postmeal glucose monitoring has a specific role in preconception diabetes care beyond what is needed to achieve the target for glycated hemoglobin. Thus, a focus on preprandial monitoring is recommended initially to assist patients in self-selection of insulin doses.

2. Implement the treatment plan and monitor glycated hemoglobin levels at 1- to 2-month intervals until stable. Then, counsel patient about the risk associated with her level. If she does not achieve a low-risk level of <1% above the upper limit of normal, consider modification of the treatment regimen, including addition of postprandial glucose monitoring. It is important to note that glycemic goals may need to be modified according to the patient's recognition of hypoglycemia and risk of severe neuroglycopenia. Outpatient management is the appropriate forum for achieving preconception glycemic goals.

Continuing Care

After the initial visit, patients should be seen at 1 to 2 month intervals depending on their mastery of the management program and the presence or absence of coexisting medical conditions. Frequent phone contact for adjustment of insulin doses and other aspects of the treatment regimen is advised as well. Once the patient has achieved stable glycemic control (assessed by glycated hemoglobin) that is as good as she can achieve, then she can be counseled about the risk of malformations and spontaneous abortions. If the risk as well as the status of maternal diabetic complications and any coexisting medical conditions are acceptable, then contraception can be discontinued. If conception does not occur within 1 year, the patient's fertility should be assessed.

Special Considerations

Hypoglycemia

It is clear from the Diabetes Control and Complications Trial that attempts to achieve normal glycemic control in patients with type 1 diabetes increase the risk of severe hypoglycemia. There is no solid evidence that such hypoglycemia is an independent risk to the developing human embryo. There is, however, clear risk to the mother. It is imperative that this risk be explained to the woman with diabetes contemplating pregnancy and that means of prevention or ultimate treatment be provided to her and her family. Inclusion of family members and close associates of the patient in both education and management is imperative. Frequent contact with the patient for readjustment of the treatment program is integral to the prevention of severe hypoglycemia.

Retinopathy

Diabetic retinopathy may accelerate during pregnancy. The risk can be reduced by gradual attainment of good metabolic control before conception and by preconceptual laser photocoagulation in women with standard indications for that therapy. Thus, a baseline dilated comprehensive eye examination is necessary before conception, and women with pre-existing diabetes should be counseled on the risk of development and/or progression of diabetic retinopathy. In settings in which a retina specialist is unavailable, other experienced examiners may be acceptable. Follow-up ophthalmological examination should be anticipated during pregnancy for all women with diabetes.

Hypertension

Hypertension is a frequent concomitant or complicating disorder of diabetes. Patients with type 1 diabetes frequently develop hypertension in association with diabetic nephropathy, as manifested by the presence of gross proteinuria. Patients with type 2 diabetes more commonly have hypertension as a concomitant disease. In addition, pregnancy-induced hypertension is a potential problem for the woman with diabetes, particularly when proteinuria in excess of 190 mg/day is present before conception or in early pregnancy. Aggressive monitoring and control of hypertension in the preconception period is advised, if for no other reason, to reduce the risk of worsening diabetic nephropathy or the development of retinopathy or clinical atherosclerosis. Angiotensin-converting enzyme inhibitors,

beta-blockers, and diuretics should be avoided in women contemplating pregnancy.

Nephropathy

Baseline assessment of renal function by serum creatinine and some measure of urinary protein excretion (urine albumin-to-creatinine ratio or 24-h albumin excretion) should be undertaken before conception and followed at regular intervals because of the potential impact of pregnancy on proteinuria and the impact of renal insufficiency on fetal growth and development. Women with incipient renal failure (serum creatinine >3 mg/dl or creatinine clearance <50 ml/min) should be counseled that pregnancy may induce a permanent worsening of renal function in >40% of patients. In subjects with less severe nephropathy, renal function may worsen transiently during pregnancy but permanent worsening occurs at a rate no different from the background. Therefore, it should not serve as a contraindication to conception and pregnancy. As mentioned above, the presence of proteinuria in excess of 190 mg/24 h before or during early pregnancy is associated with a tripling of the risk of hypertensive disorders in the second half of pregnancy. Angiotensin-converting enzyme inhibitors for treatment of microalbuminuria should be discontinued in women who are attempting to become pregnant.

Neuropathy

The presence of autonomic neuropathy, particularly manifested by gastroparesis, urinary retention, hypoglycemic unawareness, or orthostatic hypotension may complicate the management of diabetes in pregnancy. These complications should be identified, appropriately evaluated, and treated before conception. Peripheral neuropathy, especially compartment syndromes such as carpal tunnel syndrome, may be exacerbated by pregnancy.

Cardiovascular Disease

Untreated coronary artery disease (CAD) is associated with a high mortality rate during pregnancy. Evidence of coronary artery disease should be sought according to the American Diabetes Association consensus statement on the diagnosis of coronary heart disease. Successful pregnancies have been undertaken after coronary revascularization in women with diabetes. Exercise tolerance should be normal to maximize the probability that the patient will tolerate the increased cardiovascular demands of gestation.

Early Pregnancy Management

At the earliest possible time after conception, pregnancy should be confirmed by laboratory assessment (urinary or serum beta human chorionic gonadotropin). The woman should be re-evaluated by the health care team to reinforce goals and methods of management, which should remain essentially stable throughout the first trimester.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and effective preconception care of women with diabetes to prevent early pregnancy loss and congenital malformations and to reduce health care costs. Clinical trials of preconception care to achieve stringent blood glucose control in the preconception period and during the first trimester of pregnancy have demonstrated striking reductions in rates of malformations compared with infants of diabetic women who did not participate in preconception care.
- Improved glycemic control and general diabetes management in women

POTENTIAL HARMS

Risk of severe hypoglycemia: It is clear from the Diabetes Control and Complications Trial that attempts to achieve normal glycemic control in patients with type 1 diabetes increase the risk of severe hypoglycemia. There is no solid evidence that such hypoglycemia is an independent risk to the developing human embryo. There is, however, clear risk to the mother.

QUALIFYING STATEMENTS

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Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and above all, patient's values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by American Diabetes Association, may miss some nuances that are important in diabetes care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Preconception care of women with diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S76-8. [2 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 (revised 2000; republished 2004 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

The guideline was originally approved in 1995; the most recent review/revision was completed in 2000.

American Diabetes Association (ADA) position statements are reissued annually.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The recommendations in this paper are based on the evidence reviewed in the following publication:

- Kitzmiller JL, Buchanan TA, Kjos S, Combs CA, Ratner R: Preconception care of diabetes, congenital malformations, and spontaneous abortions (Technical Review). Diabetes Care 1996;19:514-41.

Print copies: Available from the American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. This summary was updated by ECRI on January 29, 2002, April 21, 2003, and March 23, 2004.

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